4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2474]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0605. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species--21 CFR Part 516

OMB Control Number 0910-0605--Extension

The Federal Food, Drug, and Cosmetic Act authorizes FDA to implement regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species (21 U.S.C. 360ccc). This statutory authority provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors who have had their drugs designated by FDA under section 573 of the Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108-282) (MUMS Act). Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species, for example, zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees.

MUMS-drug designation is completely optional for drug sponsors. The associated reporting only applies to those sponsors who request and are subsequently granted MUMS-drug designation status. Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS-drug designation as well as the annual reporting requirements for MUMS designees. Sponsors use FDA's "eSubmitter" system to fill out a series of system generated screens to submit their request and annual report electronically. To access the "eSubmitter" system, sponsors will use a previously established account. Additional information about this system is available on our website at: https://www.fda.gov/industry/fda-esubmitter.

Description of Respondents: The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

In the *Federal Register* of August 1, 2022 (87 FR 46961), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
516.20; content and format of MUMS-drug designation request	5	2	10	16	160
516.26; requirements for amending MUMS-drug designation	3	1	3	2	6
516.27; change in sponsorship of MUMS-drug designation	1	1	1	1	1
516.29; termination of MUMS-drug designation	2	1	2	1	2
516.30; requirements of annual reports from sponsor(s) of MUMS-designated drugs	26	2	52	2	104
516.36; consequences for insufficient quantities of MUMS-designated drugs	1	1	1	3	3
Total					276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection reflects an overall adjustment decrease of 88 responses and 1,086 burden hours. Upon further review since publication of the 60-day notice, we determined that the number of respondents for new designation requests decreased (from 15 to 5 respondents) due to changes in industry, while the number of respondents for annual reports increased (from 15 to 26 respondents), due to an increase in the number of sponsors holding active MUMS designations since the last renewal of this collection. We also decreased the number of responses per respondent for both the new designation request and the annual report (from five to two), based on our experience over the last 3 years.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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